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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,643	10/31/2001	Bradley T. Hyman	19603/3541 (CRF D-2694A)	2817
7590 Michael L. Goldman NIXON PEABODY LLP Clinton Square P.O. Box 31051 Rochester, NY 14603			EXAMINER LAURITZEN, AMANDA L	
			ART UNIT 3737	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/10/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/001,643

Applicant(s)

HYMAN ET AL.

Examiner

Amanda L. Lauritzen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-14, 16, 18-21, 24-30, 32, 34, 36 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-14, 16, 18-21, 24-30, 32, 34, 36 and 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>16 January 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

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Priority

1. Applicant's claim for the benefit of a prior-filed provisional application under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 10-11 and 25-27 (and those depending therefrom) are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Examiner understands that the method is adapted for imaging tissue and detecting neurodegenerative disease, but the claim must recite it in such a way that the tissue and disease are not actually being claimed as the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 8-14, 16, 18-21, 24-30, 32, 34, 36 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (US 6,329,531) in view of Hochman (US 2003/0236458).

Turner et al. disclose a method for detecting a neurodegenerative disease comprising activating brain tissue by application of radiation under conditions to promote simultaneous photon excitation of the brain tissue and to emit a fluorescence

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characteristic (refer to the Abstract in which the disease diagnosis is Alzheimer's by applying radiation with wavelength in the visible to NIR region for detection of amyloid plaques in the brain). The photo-active compounds disclosed by Turner et al bind to the A-beta plaques (col. 2, lines 58-64). In-vivo detection of amyloid plaques is characterized as having a laser-induced fluorescence characteristic differing from that in normal tissue and is disclosed to produce an image (col. 2, line 65 – col. 3, line 2; also col. 16, lines 47-52 for applying laser light with wavelength of 740nm). The method of Turner also specifies identification of neurofibrillary tangles (col. 1, line 21).

Turner et al. disclose all features of the invention as substantially claimed as detailed above but are silent with regard to the specifics of the pulsed radiation, carrying out the procedure on a skull that has been thinned or opened, or comparison to a standard fluorescence for making diagnosis. In the same field of endeavor, Hochman discloses diagnosing neurological disorders with an "invasive or semi-invasive" procedure that Examiner understands would include removal of a portion of the skull and/or thinning of the skull to enable access to the brain (par. 42). Additionally, Hochman describes optical sources providing either continuous or non-continuous (i.e., "pulsed") illumination (par. 41; also par. 146). Hochman discloses comparing patient data to a control and/or standard data set for the purpose of diagnosis and also acquires fluorescence naturally characteristic to the tissue without administering a contrast agent (i.e., "autofluorescence") at par. 45. Hochman further discloses application of energy with a wavelength of about 800nm to analyze deeper areas of tissue (par. 144). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified the method of Turner to include comparison to a standard data set in order to make a

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diagnosis (as taught by Hochman at par. 45) with removal of impeding bone structure or thinning of the skull as is implied under the invasive brain procedure of Hochman (par. 42) so that pulsed illumination of the area of interest would be possible. It would have been obvious to one of ordinary skill in the art at the time of invention to have provide a pulse width in the femtosecond range with a mode-locked laser in order to concentrate power delivered over a very short time period.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chance (US 5,062,428) for Method and Device for In Vivo Diagnosis Detecting IR Emission by Body Organ, in which a "thin cranium... allows or enhances detection of such [visible light] wavelengths" (col. 4, lines 50-52).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



A. Lauritzen
3/30/2007



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